

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amended After Comments)

902 KAR 45:180. Permits and fees for food processing[~~manufacturing~~] plants, food storage warehouses, salvage processors and distributors, cosmetic manufacturers, and certificate of free sale.

RELATES TO: KRS 217.015, 217.025, 217.035, 217.037, 217.085, 217.095, 217.155, **21 C.F.R. Parts 113, 114, 120, 123**

STATUTORY AUTHORITY: KRS 217.125(1), (2)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act. KRS 217.125(2) requires the secretary to provide by administrative regulation a schedule of reasonable fees to be paid by food **processing**[~~manufacturing~~] plants, food storage warehouses, salvage distributors, salvage processing plants, and cosmetic manufacturers for permits to operate and for inspection activities carried out by the cabinet. This administrative regulation establishes the schedule of fees.

Section 1. **Definitions. (1) "Ready-to-eat" means food that is in a form that is edible without washing, cooking, or additional preparation by the food plant or the consumer to achieve food safety, and is expected to be consumed in that form.**

(2) "Specialized processes" means foods processed under 21 C.F.R. Parts 113, 114, 120, or 123.

Section 2. Classification. Food processing and storage facilities shall be classified by the highest risk level of the food processed or stored.

(1) A facility shall be classified as a high risk food plant or risk level 1 if the facility:

(a) Is engaged in international, interstate, statewide, or regional distribution; and

(b) Uses one (1) or all of the following manufacturing processes:

1. Time and temperature controlled foods that are ready-to-eat;

2. High risk foods that are considered ready-to-eat; or

3. Foods that require specialized processes to decrease risk potential.

(2) A facility shall be classified as a medium risk food plant or risk level 2 if the facility processes foods that are either ready-to-eat foods or potentially hazardous foods, but not both.

(3) A facility shall be classified as a low risk food plant or risk level 3 if the facility processes foods that are not time and temperature controlled.

Section 3. Fees. (1) A permit fee shall be required for inspections conducted by the cabinet or the local health department to determine compliance with:

(a) 902 KAR 45:080 for a salvage distributor or a salvage processing plant;

(b) KRS 217.025, 217.035, and 217.037 for a food **processing**[~~manufacturing~~] plant or food storage warehouse; or

(c) KRS 217.085 and 217.095 for a cosmetic manufacturer.

(2) **The[A]** fee for the inspection of a food **processing**[~~manufacturing~~] plant or food storage warehouse shall be:

(a) Assessed according to the:

1. Total yearly gross income from product sales of the facility; and

2. Highest risk level of commodity manufactured **by or stored at the facility:** and

(b) Calculated as established in this paragraph.

1. If the income is less than \$100,000 per year, the fee:

a. For risk level 1 shall be \$250;

b. For risk level 2 shall be \$200; or

c. For risk level 3 shall be \$150.

2. If the income is equal to or greater than \$100,000 but less than \$500,000 per year,

the fee:

a. For risk level 1 shall be \$400;

b. For risk level 2 shall be \$350; or

c. For risk level 3 shall be \$300.

3. If the income is equal to or greater than \$500,000 but less than \$1,000,000 per year,

the fee:

a. For risk level 1 shall be \$1,200;

b. For risk level 2 shall be \$750; or

c. For risk level 3 shall be \$450.

4. If the income is equal to or greater than \$1,000,000 per year, the fee:

a. For risk level 1 shall be \$2,800;

b. For risk level 2 shall be \$1,500; or

c. For risk level 3 shall be \$1,000[=

(a) High risk plant – \$2,400;

(b) Medium risk plant – \$1,350; or

(c) Low risk plant – \$750].

(3) A fee for the inspection of a cosmetic manufacturer shall be \$150[300].

(4) A request for a certificate of free sale or export authorizing a Kentucky food **pro-**
cessing[manufacturing] plant holding a valid permit to operate to export a product outside of
the United States shall be accompanied by a service fee of fifty (50) dollars for each certificate
requested.

(5)[Section 2. Payment of Fees.] Fees shall be made payable to the Kentucky State
Treasurer and forwarded to the Kentucky Department for Public Health, Food Safety Branch,
275 East Main Street, Frankfort, Kentucky 40621.

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 6, 2020

FILED WITH LRC: October 8, 2020 at 2:22 p.m.

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Julie Brooks or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the
amount of the fees paid by food processing plants, food storage warehouses, cosmetic manu-
facturers, salvage processors and distributors, and requests for certificates for free sale.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the fee structure to help support the department costs for permitting and inspecting food processing plants, food storage warehouses, cosmetic manufacturers, salvage distributors, salvage processing plants, and for issuing certificates of free sale.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 217.125 authorizes the secretary to promulgate regulations to establish a fee schedule for food processing establishments, food storage warehouses, salvage distributors, and salvage processing plants. KRS 217.155 authorizes the cabinet or its agents to inspect any factory, warehouse, or establishment in which cosmetics are manufactured. This administrative regulation outlines the schedule of fees to be paid for permit and inspection.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist with addressing the cost to administer food and cosmetic permitting and inspection programs.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This is an Amended After Comments version of a new administrative regulation, not an amendment to an existing administrative regulation.

The Amended After Comments version of this new administrative regulation revises the proposed fee structure to be tiered based on income and risk level.

(b) The necessity of the amendment to this administrative regulation: This is an Amended After Comments version of a new administrative regulation, not an amendment to an existing administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is an Amended After Comments version of a new administrative regulation, not an amendment to an existing administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is an Amended After Comments version of a new administrative regulation, not an amendment to an existing administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: There are 1,072 food processors and seventy-seven (77) cosmetic manufacturers registered with the department.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: All permitted food processing plants and storage warehouses will pay a fee based on the total yearly gross sales income and identified risk category level associated with the type of food being processed or stored. Cosmetic manufacturers are required to manufacture products in a commercial kitchen and the Food Safety Branch staff are responsible for inspecting all commercial kitchens.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): The current fee structure for food processing is based on the square footage for the facility and ranges from \$120 to \$600. This administrative regulation changes the fee structure to be based on yearly gross sales and the risk of the food manufactured. A low risk food processor who makes less than \$100,000 a year will pay \$150, while a low risk food processor who makes over one (1) million dollars a year will pay \$1,000. Cosmetic manufacturers will now be required to pay a \$150 fee for inspection.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): All food processing plants, and cosmetic manufacturers are required to be inspected and permitted by the cabinet. The fees paid for inspection and permitting help to ensure food processing plants and cosmetic manufacturers are in compliance with federal and state laws. Food processing plants with a higher risk category level will be inspected at a higher frequency as they have the greatest food safety risk.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs initially.

(b) On a continuing basis: There are no additional costs on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Agency funds and revenue received from permitting and inspection fees continue to be used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: This administrative regulation does increase the fees paid by food processing plants and institutes a new fee for cosmetic manufacturers. There is no increase in funding necessary for this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees.

This administrative regulation establishes the fees associated with operating a food processing plant or storage facility, a cosmetic manufacturer, and for the issuance of a certificate for free sale. The administrative cost to the cabinet is approximately \$150 per hour for inspectors. This cost includes the salary of the inspector, fiscal year 2018 Kentucky Employee Retirement System (KERS) and Federal Insurance Contributions Act (FICA) contributions, and health and life insurance costs.

The risk level of a food processing plant or food storage facility has an impact on the length of time required to conduct an inspection as well as the number of inspections completed per year.

Cosmetic manufacturers are currently subject to inspection but are not assessed a fee for permitting and inspection activities. This administrative regulation adds a fee of \$150 for the permitting and inspection activities of the cabinet.

(9) TIERING: Is tiering applied? Tiering is applied. The fee structure will be based on the total yearly sales income and the risk of the food being produced. Those making less than \$100,000 a year will pay a lower fee than those making over one (1) million dollars a year.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment impacts the Department for Public Health, Division of Public Health Protection and Safety, Food Safety Branch, and all local health departments.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 217.125 and KRS 217.811.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The

change in fee structure will generate an estimated \$796,996 from all entities regulated under this administrative regulation in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The change in fee structure will continue to generate an estimated \$796,996 in subsequent years.

(c) How much will it cost to administer this program for the first year? The current cost to administer the food processing inspection program is \$1,080,900. There is no anticipated increase in costs to administer permitting and inspection of food processing plants, food storage warehouses, food service establishments, retail food stores, cosmetic manufacturers, and vending machine companies this first year.

(d) How much will it cost to administer this program for subsequent years? There will be no change in program cost.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 21 C.F.R. Parts 113, 114, 120, and 123

2. State compliance standards. This administrative regulation adopts the federal requirements for food processing, packaging, storage, and distribution operations. The Food Safety Branch in the Department for Public Health was directed by the federal Food and Drug Administration (FDA) on which code of federal regulation to adopt to be in full compliance with the FDA food manufacturing standards.

3. Minimum or uniform standards contained in the federal mandate. KRS 217.125(1) authorizes the cabinet to promulgate regulations consistent with those promulgated under the federal act and the Fair Packaging and Labeling Act.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? No

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. There are no different, stricter, or additional responsibilities or requirements.